



OFFICE OF THE SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

10 APR 1995

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)  
ASSISTANT SECRETARY OF THE ARMY (RDA)  
ASSISTANT SECRETARY OF THE NAVY (M&RA)  
ASSISTANT SECRETARY OF THE NAVY (RDA)  
ASSISTANT SECRETARY OF THE AIR FORCE  
(MRAI&E)  
ASSISTANT SECRETARY OF THE AIR FORCE (SAF/AQ)  
PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE  
HEALTH SCIENCES  
DIRECTOR, DEFENSE NUCLEAR AGENCY  
DIRECTOR, ADVANCED RESEARCH PROJECTS AGENCY

SUBJECT: Department of Defense (DoD) Policy for Compliance with  
Federal Regulations and DoD Directives for the Care and  
Use of Laboratory Animals in DoD-Sponsored Programs

References:

(a) Title 7, United States Code, Sections 2131-2156,  
The Laboratory Animal Welfare Act of 1966, PL 89-544,  
as amended PL 94-279, 1976, and PL 99-198, 1985.

(b) Review of the Use of Animals in the Department of  
Defense Medical Research Facilities, Inspector General  
Department of Defense, February 1994.

(c) Review of the Use of Animals in Department of  
Defense Contract Research Facilities, Inspector  
General Department of Defense, August 1994.

Definition:

(a) Animal means any dog, cat, non-human primate, or  
any other live vertebrate animal which is being used  
or is intended for use for research, training, testing,  
or experimentation purposes. For this Policy Guidance,  
it includes birds, rats of the genus Rattus and mice of  
the genus Mus bred for use in research, training,  
testing or experimentation purposes. The term excludes  
animals used for ceremonial or recreational purposes,  
military working animals, and animals intended for use  
as livestock and poultry as food or fiber; or,  
livestock or poultry used or intended for use for  
improving animal nutrition, breeding, management, or  
production efficiency, or for improving the quality of  
food or fiber.

(b) DoD-Sponsored programs means any study, proposal,  
or design for animal experimentation or demonstration  
in Research Development, Test, and Evaluation (RDT&E),  
clinical investigation, or instructional program  
conducted or funded by grant, award, loan, contract, or  
cooperative research and development agreement (CRADA).

Reference (a) has been accepted by the Department of Defense (DoD) in the development of DoD Directives and policy guidance. References (b) and (c) contain recommendations which have been endorsed by the Department. The purpose of this policy memorandum is to implement the recommendations contained in references (b) and (c).

DoD components that utilize animals in DoD-supported programs shall be aware of the attached DoD Directive 3216.1, "Use of Laboratory Animals in DoD Programs," appended as attachment (1). It is currently pending signature and will supersede the current DoD Directive 3216.1 dated February 1, 1982. Additional policy guidance is as follows:

a) In DoD component facilities conducting animal-based programs, an alternate to the non-affiliated member of the Institutional Animal Care and Use Committee (IACUC) shall be designated for IACUCs having a single non-affiliated member. The non-affiliated member(s) or alternates must receive a minimum of eight hours training. At least four hours of the training shall address the regulatory responsibilities and proper techniques on animal protocol review processes. An additional minimum of four hours of training will address humane care and ethics issues dealing with animal use. All DoD Components conducting animal use programs as defined shall have training programs for non-affiliated IACUC members in place by 1 October 1995.

b) All DoD component facilities maintaining animals used in research, testing, or training shall apply for accreditation by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). The Office of the Director, Environmental and Life Sciences, Pentagon Room 3D129, Washington, D.C. 20301-3030 is the central point of contact to maintain cognizance over the application or continuation of AAALAC accreditation. All DoD facilities shall furnish copies of AAALAC accreditation status to that office. Absence of accreditation shall be explained with a plan of action and milestones to obtain accreditation.

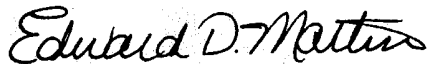
The following recommendations from the DoD Inspector General have been adopted as policy and shall be fully implemented by DoD Components which use animals in DoD-sponsored programs.

a) The DoD standard protocol format appended as attachment (2) shall be implemented by 1 October 1995. All intramural protocols involving animal use submitted after 1 October 1995 shall use the standard format. Extramural contractor proposal submissions need not use the standard format; however, the contractor shall provide all pertinent information contained in the standardized protocol format.

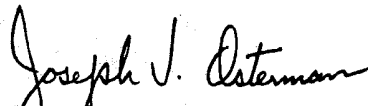
b) All DoD component facilities that utilize animals in research, testing and training shall implement the DoD standardized semi-annual program review checklist appended as attachment (3) immediately. Accompanying the checklist is a detailed outline of program review as contained in the NIH Guide for the Care and Use of Laboratory Animals. The Guide is the primary reference which is used by AAALAC in the accreditation process. The checklist shall be completed as a part of the semiannual IACUC program and facility review process. The semi-annual IACUC reports shall contain a copy of the checklist or indicate that the checklist was used as the basis of the program and facility review. A majority of members of the IACUC shall sign the report and include a statement indicating the presence or absence of minority opinions.

c) Commanders, and Directors of DoD component facilities shall support and, as necessary, develop animal care and use training programs for personnel associated with animal use programs, and encourage certification for all personnel involved in the care, use and treatment of laboratory animals.

As of 1 October 1995, DoD components shall report all animal-based protocols in the required format redacted for public release to the Defense Technical Information Center (DTIC). Selected fields of the DTIC report will be made accessible to the public through the INTERNET.



Edward D. Martin  
Principal Deputy,  
Assistant Secretary of  
Defense (Health Affairs)



Joseph V. Osterman  
Director, Environmental  
and Life Sciences

Attachments:

- (1) Pending DoD Directive 3216.1
- (2) Standard Protocol Format
- (3) Standard Semi-annual Checklist